

Attorney Docket # 5434-16

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Tom MINER, *et al.*

Serial No.: 10/768,760

Filed: January 29, 2004

For: Intravenous Delivery System

Examiner: Osinski, Bradley James
Group Art: 4111

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

S I R:

Applicants request a panel review of the issues on appeal in the above-referenced application. The present request is filed concurrently with a Notice of Appeal, and is filed before any Appeal Brief. No claim amendments are submitted with this request. The review is requested for the reasons set forth below.

Papers of Record to be Considered

Claims 1-55 are pending herein, with claims 1, 22, 24, 31, 40, 43, 49 and 55 being independent. The claims now present are set forth in the Response mailed April 22, 2009 and a description of the invention and applicants' discussion concerning the inapplicability of the art then of record is contained in that same paper. The final Office Action was mailed August 3, 2009. The description and arguments of record will not be re-presented, and familiarity therewith is presumed.

It is pointed out, however, that this is the second Pre-Appeal Brief Request for Review for this application. In the first "Request", applicants sought review of the Examiner's rejection of the claims as anticipated by U.S. Patent No. 6,336,916 (Bormann). In this (second) Request applicants seek review of the Examiner's final rejection of the claims as rendered obvious by Bormann and one or more secondary references.

Errors in Final Office Action

1. In response to the January 22, 2009 Office Action, applicants pointed out that the art then applied, including Bormann, did not teach a wettable vent plug which seals the drip chamber when the vent plug is wet. (prior response, p. 21). In response to that argument, the Examiner stated (final Office Action p. 12, para. vv) that he "does not find any sealing causation in the claims". However, each independent claim recites that the vent plug, when wetted, prevents the outflow of air. Thus, the Examiner erred by overlooking this feature.

2. In the response to the January 22, 2009 Office Action, applicants pointed out that the art did not show the use of a wettable vent plug located at the desired level of the reservoir, oriented in a direction transverse to the direction of drip flow through the drip chamber. The Examiner attempts to overcome the deficiency in the art by applying a newly cited reference, U.S. Patent No. 6,213,986 (Darling, Jr.) which discloses a liquid flow rate control device having vent tubes **90** and **94** oriented transverse to the direction of drip flow. However, each vent tube **90**, **94** contains a filter **92**, **96** which is *not wettable* to seal the drip chamber, and which is positioned above the reservoir, such that filters **92b** and **96** avoid getting wet.

The Examiner has made no showing of how one of ordinary skill in the art would combine the primary reference (Bormann) with the secondary reference of Darling, Jr. to provide a drip chamber having a vent that is: (a) at a location which sets the desired level of the reservoir;

(b) oriented in a direction transverse to the direction of drip flow; and (c) plugged with a wettable, sealable, material that will seal the opening in the drip chamber when the level of the reservoir reaches the vent plug location.

The Examiner has engaged in impermissible “cherry-picking” of features found in the prior art, without considering the teachings of the art *as a whole* and has offered no rationale as to why one of ordinary skill in the art would select just those features and ignore the remainder of the features of the references, to arrive at the claimed invention.

Discussion

1. The Claims expressly recite the feature of the invention that sealing is caused by the wetting of the vent plug.

The Examiner’s statement that he could “not find any sealing causation in the claim” is made with reference to applicants’ argument in the Response mailed April 22, 2009 (p. 23, lines 20-22) with respect to the applicability of Knighton (*see*, final Office Action, page 12, para. vv.).

It is noted that Knighton is applied only against claims 2-5, 43-48, 50 and 52-55. However, claims 2-5 and 54 depend from independent claim 1, which states:

“wherein wetting of said vent plug by the reservoir prevents entry of air through said vent plug to said drip chamber and prevents the exit of solution from said drip chamber through said vent plug.” (final three lines)

Claim 43 is independent, and claims 44-48, 52 and 53 depend therefrom. Claim 43 includes the limitation:

“a termination end vent plug for preventing the escape of solution through said vent of said termination end cap upon wetting of said termination end vent plug by the solution.” (final three lines)

Claim 50 depends from claim 49 which includes the limitation:

“discontinuing said restriction step upon wetting of said vent plug by said reservoir” (next-to last line)

Claim 55 is independent and includes the limitation:

“wherein said drip chamber vent plug and said termination end cap cooperate to allow the formation of said reservoir to proceed while purging of said entrapped air from said patient conduit until at least one of said drip chamber vent plug and said termination end vent plug is wetted and thereby sealed.” (final four lines)

Thus, each claim against which the Examiner has applied Knighton includes a limitation relating to “sealing causation”, which the Examiner has stated he could not find. The Examiner’s failure to consider this limitation is error, requiring withdrawal of the rejection based on Knighton.

2. Making the primary combination applied by the Examiner would not result in the claimed invention.

Bormann, *et al.* teach the use of a wettable, sealable plug (material 10) that is oriented parallel to the direction of drip flow (Figs. 1-5) to set the level of solution in the drip chamber, but require the use of a lengthy tube (vent 3, comprising material 10, port 4, gas passageway 5 and port 30) oriented parallel to the drip flow to permit the escape of air in the drip chamber. Vent 3 is oriented to prevent observation of the drip flow from certain angles, such as the right side in Fig. 1. Bormann, *et al* themselves expressly disparage the prior art as potentially “lead[ing] to difficulties in monitoring the drip rate.” (col. 1, lines 52-54), thereby recognizing the need to monitor the drip rate. Nonetheless, in *each* embodiment disclosed in the patent, Bormann, *et al* teach the use of a gas escape vent which would still partially obscure the drip.

Bormann, *et al* do, in fact, teach the use of a port 30 which allows for the outflow of gas from the device in a direction which is *transverse* to the drip flow, in Fig. 8. Bormann, *et al.* teach that this embodiment includes moving the wettable material 10 *even higher*, to a level that is *above the top of the drip chamber*, while leaving a passageway 6 within the drip chamber which obscures the drip flow rate when observed from the right of Fig. 8. Thus, Bormann, *et al.*

do not teach placing an opening on the side of the drip chamber, and filling that opening with a wettable, sealable material that will allow the sealing of the opening when the liquid reservoir reaches the vent plug, thereby setting the level of the reservoir. To the contrary, Bormann, *et al.* teach that *all* orientations of the outflow of gas with wettable materials are accompanied by a drip-flow-obscuring port.

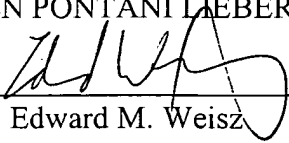
The Examiner may not simply choose one aspect of Darling, Jr., namely that an opening may be placed transverse to the direction of drip flow, without acknowledging that Darling, Jr. teaches such an opening should be placed *above* the desired level of the reservoir, and filled with a non-wettable, non-sealable, material. This is particularly true where Bormann, *et al.* also teach the use of an opening oriented transverse to the drip flow, with the opening located *above* the desired level of the reservoir.

It must also be noted that Darling, Jr. teaches a completely different system for controlling the level of the reservoir, namely a complex system involving two separate valves 120, 140 that float to close orifices 136, 152, respectively, and that, under that system, the level of solution in the lower chamber 62 fluctuates greatly between the lower limit 82 and upper limit 84, rather than being fixed at the desired level as in the claimed invention.

For all these reasons, therefore, it is submitted that the claims are allowable.

Respectfully submitted,
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